EXHIBIT 1
DATE 2-14-07
HB 536

Legislation To Strengthen Protections For Montana Consumers Against The Threat Of Counterfeit Drugs

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State of Montana

House Bill No. 536

Wholesale Licensure and Prescription Medication Integrity Act

February 14, 2007

Testimony Of Matt Van Hook, Engel & Novitt
On Behalf Of PhRMA

Mr. Chairman and members of the subcommittee, thank you for the opportunity to appear before you today, and provide input on this important legislation. I am a partner with a small Washington, D.C. law firm that focuses on Food & Drug matters, particularly the development and FDA approval of new drugs, and issues related to the drug distribution system. I am appearing here today on behalf of the Pharmaceutical Research and Manufacturers of America. PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which in 2005 (the latest data available to date) invested over $39 billion in discovering and developing new medicines. PhRMA companies are the source of nearly all new drugs discovered and marketed throughout the world, and they are subject to very heavy regulatory oversight by the U.S. FDA in terms of what drugs may be marketed, and where and how they are produced. PhRMA is keenly interested in helping to assure the integrity of the distribution system for these medicines, so that for example when you go to your local pharmacy here in Helena, you can be assured you are dispensed exactly what your doctor ordered.

PhRMA supports H.B. 536, with several amendments that I will discuss, because it would establish important improvements in consumer protections here in Montana for the drug distribution system, in some respects reflecting recent reforms in Federal law, and in other respects providing important supplemental protections designed to close loopholes in Federal law. In summary, HB 536 would achieve these increased levels of protection by: (1) strengthening requirements regarding the licensing of wholesale distributors; and (2) assuring that the chain of custody from Manufacturer to Pharmacy is documented ("pedigreed") to the extent consistent with good public policy and the best available technology. These reforms build on, and are consistent with, both the existing Federal scheme, and similar reforms now being implemented by your sister States.

I would like to first briefly outline the key provisions of HB 536, and then show how they help respond to the increasing challenge of counterfeit drugs. Both wholesaler licensing and pedigree requirements have their roots in consumer protections first put in place at the Federal level nearly 20 years ago, as a result of a series of oversight hearings that documented how counterfeits were threatening the U.S. Unfortunately, those threats have grown; however, we can thank vigilant law enforcement authorities at both the State and Federal level for keeping counterfeiters at bay even as we develop new compliance tools, and we can also look toward promising new technology that is expected to increase the integrity of our drug distribution system significantly.

Key Anti-Counterfeit Reforms In HB 536

Tightened Licensing Of Wholesale Distributors

- Section 3, page 5, would require every person engaged in wholesale distribution in Montana to be licensed by the Board.

- In addition to the minimum requirements of Federal law (see, e.g., 21 CFR Part 205), this generally would include identification of a Designated Representative, and detailed criminal background, and submission of a bond (see Section 3, subsections 2(g), 3-11, pages 5-8).

- As with Federal law, manufacturers engaged in wholesale distribution would be subject to licensing. However, because manufacturers have not been associated with the concerns that have led FDA and other states to tighten oversight (unlike other wholesalers, manufacturers only sell, they do not *buy* drugs in the wholesale market), manufacturers distributing their own FDA-approved drugs should be exempted from the more stringent qualifications required for licensing. Accordingly, it is recommended that Section 3(1) be amended, to add the following new sentence at the end of line 9, page 5:
  "Manufacturers engaged in wholesale distribution are subject to licensing. However, information and qualification requirements for licensure, beyond that required by federal law or regulation, do not apply to manufacturers distributing their own United States Food and Drug Administration-approved drugs, unless particular requirements are deemed necessary and appropriate following rulemaking."

Pedigree Requirements

- HB 536 conforms to the minimum requirements of Federal law by requiring pedigrees for any transactions by wholesalers that are not Authorized Distributors of Record (ADRs), and also closes the Federal ADR loophole by requiring pedigrees even for ADRs for any drugs that

leave, or have ever left, the Normal Distribution Channel (as defined in Section 2(10), page 2, line 23 to page 3, line 5; Pedigree Requirements are set forth in Section 5, page 9). This limitation of distributions which may be non-pedigreed reflects the concerns of state legislatures and pharmacy boards in states such as Nevada and Florida, which have responded to an influx of counterfeit activity with extended pedigree requirements as well as greater licensing scrutiny.

- The bill also contemplates the advent of electronic track & trace pedigree technology, by authorizing the Board of Pharmacy to determine when such e-pedigree technology is available across the entire pharmaceutical supply chain (with implementation no sooner than July 1, 2010). See Section 5(3), page 9, lines 12-15. Because of the uncertainty regarding exactly when this important technology will be able to be put into place, it is recommended that this provision be amended to give the board authority to extend the implementation date by one year increments; the additional sentence could be added to the end of Section 5(3), on page 9, line 15:
  "Such date may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain."

Unlawful Acts and Enforcement

- Section 7 (pages 10-11) lists 13 specific "prohibited activities" (Section 7(1)(a-l) that would be made unlawful, including failing to obtain a license (p. 11, line 2), unauthorized sales or distributions (p. 11, lines 6-8), failing to maintain, provide, obtain, pass, or authenticate a pedigree (p.11, lines 11-12), and adulteration or misbranding (except with regard to manufacturers pursuant to FDA approval; see page 11, lines 17-22).

- Any person violating the provisions of Sections 1-8, including the prohibited activities, would be guilty of the criminal penalties established in Section 8 (page 12, lines 2-8). Penalties would range from up to 15 years and up to a $50,000 fine for negligent acts, to up to 25 years and up to $500,000 for knowing acts. .

Counterfeiting Abuses Justify Passage Of HB 536

The concerns driving the need for this legislation were first widely documented during a series of Congressional hearings in the mid-1980's, which led to passage of the federal Prescription Drug Marketing Act (PDMA). Congress found that so-called "secondary wholesalers," rather than distributors with whom the manufacturer had established an "ongoing relationship" to distribute its drugs,

were the source of counterfeit and adulterated drugs.[1] In response, two key consumer protections were added to the Federal Food, Drug, and Cosmetic Act:

> (1) *Pedigree*: a requirement that unauthorized distributors provide before each wholesale distribution a "statement . . . identifying each prior sale, purchase or trade of such drug."
>
> (2) *Wholesaler Licensing*: a prohibition on engaging in wholesale distribution in interstate commerce "unless such person is licensed by the State" in accordance with minimum standards and guidelines issued by FDA.[2]

FDA has established several useful websites, documenting the challenge of counterfeit drugs,[3] and providing a range of PDMA- and pedigree-related resources and references. The PDMA/Pedigree site includes detailed explanations of the decision to let the pedigree regulations go into effect as of December 1, 2006 (driven by the recognition that electronic track & trace technology is not imminently available), and the agency's views regarding the implications of pedigree-related litigation now pending in the E.D.N.Y.[4]

In recent years, state authorities have confronted increasingly alarming counterfeiting situations, leading Florida for example to pass its pioneering wholesaler reform law in 2003. The experience of Florida with wholesaler practices of concern was documented in a 2003 Statewide Grand Jury Report by Florida's Attorney General,[5] which illustrates the need for every state, ***including Montana***, to tighten wholesaler licensing and pedigree requirements:

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[1] "The Oversight Subcommittee's investigation found that most of the drugs that were counterfeits, stolen, expired, or obtained through fraud were handled by secondary wholesalers, who were not authorized to distribute that manufacturer's product." H.R. Rep. No. 76, 100th Cong., 1st Sess. 17 (1987). See also *Dangerous Medicine: The Risk to American Consumers From Prescription Drug Diversion and Counterfeiting,* 99th Cong., 2nd Sess., (Committee Print 99-Z 1986) (Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Hon. John D. Dingell, Chairman). Among the oversight findings: "The realities of the wholesale marketplace have combined to create a system in which a large amount of attractively priced pharmaceuticals are constantly available, some of which are not safe or effective. The physical movement, conditions of storage, and, in some cases, even the origins of much of this merchandise is unknown to the first, second, or third level buyer, who in effect plays a form of Russian roulette. This situation cannot be allowed to continue." *Dangerous Medicine*, p. 20.

[2] The pedigree requirement is codified at 21 U.S.C. §353(e)(1), FD&C Act §503(e)(1). Implementing regulations are in 21 CFR §203.50. Requirements regarding state licensing of wholesalers are codified at 21 U.S.C. §353(e)(2), FD&C §503(e)(2), with implementing regulations in 21 CFR Part 205.

[3] FDA Counterfeit Drugs website:
http://www.fda.gov/oc/initiatives/counterfeit/default.htm

[4] FDA PDMA/Pedigree website:
http://www.fda.gov/cder/regulatory/PDMA/default.htm

[5] Florida Attorney General – Statewide Grand Jury Report re Rx Wholesalers

Florida Statewide Grand Jury Findings:

- Florida investigators reported "shocking and disturbing" evidence of counterfeiting, with "potential profits" for corrupt wholesalers "rival[ing] those found in narcotics trafficking." (p. 4)
- *Methodology:* counterfeiters relabel drugs "to hide the fact that they have expired, been previously dispensed, or illegally imported; to falsely overstate their strength (sometimes by as much as 2000%); or to pass off some other substance as a genuine pharmaceutical." (p. 3)
- *Wholesaler missteps show up in pharmacies:* "One case concerned a father who repeatedly injected his son [with 'growth hormone' that turned out to be insulin]. He did not buy that medication out of a car trunk or a back alley. Those drugs were traced to a legitimate pharmacy in Orlando, Florida, but it is obvious this mislabeled, adulterated product was brought into the stream of commerce by some counterfeiter. **Had the wholesaler bothered to check the pedigree by verifying the transactions, it would have discovered that the drugs could not be traced to the manufacturer.**" (p. 22)
- *Federal ADR loophole a concern:* "Wholesalers state that, in their interpretation, if they meet the definition of an Authorized Distributor of Record (ADR) for a particular manufacturer, then they are exempt from the requirements to provide a pedigree paper . . . regardless of where the wholesaler acquired the drugs being sold. **That is, even if a wholesaler purchases Procrit [for treatment of anemia in cancer/kidney patients] out of a car trunk, they believe that they are not obligated to provide a pedigree paper . . . .**" (p. 12)

There is a reason why Congress exempts manufacturers from passing a pedigree, and why states have found no reason to subject manufacturers engaged in distributing their own drugs from additional qualifications for wholesale licensure beyond the minimum requirements in federal law: manufacturers have not engaged in the kind of "gray market" activity that some wholesalers have engaged in, which has resulted in the introduction of counterfeited drugs into the U.S. distribution system, and even onto the shelves of some U.S. pharmacies. Yes, many manufacturers do engage in distributing their own drugs, and when they do may properly be subject to licensing as 'wholesalers.' But unlike manufacturers, those whose primary business is wholesaling not only engage in distributing drugs – they also necessarily must BUY drugs, and that is why it is good public policy to subject such wholesalers (and not manufacturers) to stricter licensing requirements to help assure the integrity of the drug distribution system.

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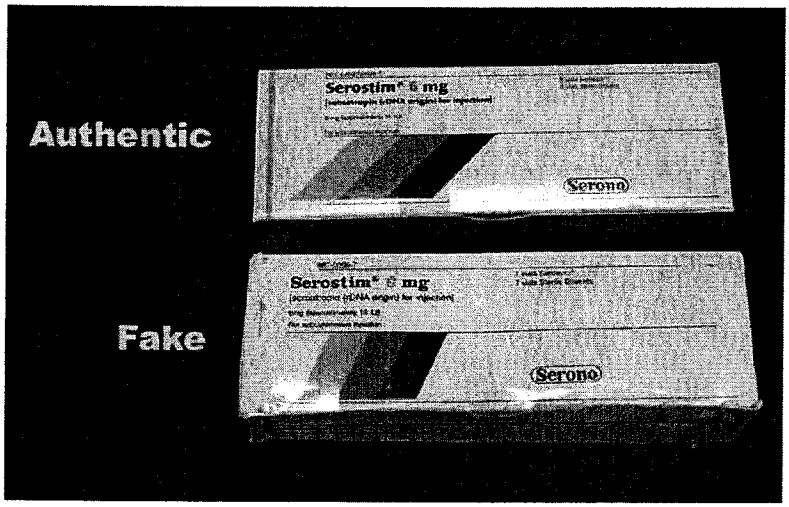
http://myfloridalegal.com/pages.nsf/4492D797DC0BD92F85256CB80055FB97/09558F82389E020785256CDA006DB01A?OpenDocument

Here is an example of counterfeit human growth hormone, from FDA's counterfeit drug web page:[6]

Counterfeit duplication of the packaging for an injectable drug.



That very drug is considered by Florida officials to be one of the top counterfeit drugs, and it was found by Florida officials to have been the subject, in one instance of counterfeiting that was uncovered, of at least 8 wholesaler-to-wholesaler resales (so-called lateral transactions), including from a New York wholesaler (listed as an ADR), to a Texas wholesaler, to a Missouri wholesaler, to three Florida wholesalers in Boca Raton and Miami. A state pharmacy bureau official, in relating this actual distribution scenario, asked rhetorically "What's wrong with this picture?".[7] What's wrong is that such secondary, or "gray market" transactions make little if any economic sense, yet they provide an entry point for counterfeit, stolen, outdated, and illegally diverted drugs to enter the U.S. drug distribution system, and ultimately to end up on the shelves of American pharmacies.[8]

The figure below (on the following page) shows how alternative distribution scenarios, involving both wholesalers that are ADRs and those that are not, can increase the opportunity for counterfeit and adulterated drugs to be purchased from illegitimate sources and enter into the U.S. drug distribution system:

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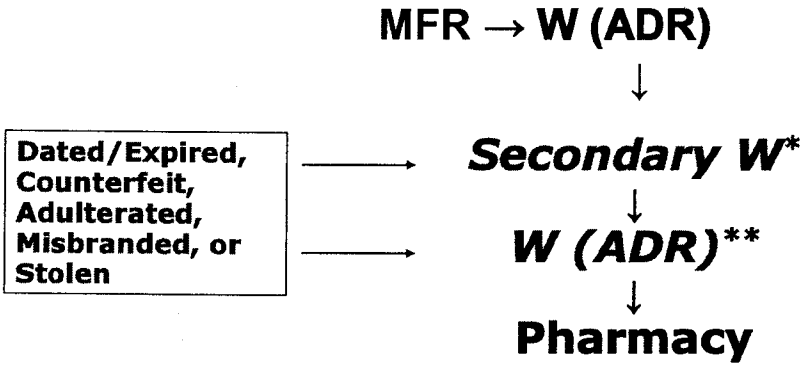
[6] http://www.fda.gov/oc/initiatives/counterfeit/default.htm

[7] Presentation by Susan Stovall, Florida Bureau of Statewide Pharmaceutical Services, to a counterfeit drug conference sponsored by the Food and Drug Law Institute, Chicago, Illinois, May 4, 2004, slide #18.

[8] See Stovall presentation, slides 3 & 4.

Multiple Transactions Increase Risks Of Counterfeit Entering Drug Distribution



* Federal pedigree required, if W is not ADR

** No federal pedigree required, regardless of source of drug (federal ADR loophole), if W = ADR

This distribution scenario shows where counterfeit drugs have entered the distribution channels, as documented by both Congress, and the Florida Grand Jury report. Pedigree papers are not perfect, but they at least provide state and federal compliance officials with an excellent enforcement tool; a falsified or missing pedigree can provide a "smoking gun" for prosecutors. More importantly, reform measures like HB 536 can improve on the existing system by closing the "federal ADR loophole," demonstrated in the above scenario where, under federal law, the second ADR Wholesaler would not be required to pass a pedigree. ***Under the proposed Montana law, each of the listed wholesalers after the first ADR would be required to pass a pedigree, whether they had ADR status or not, because of the fact the drug had left, or ever left, the normal distribution channel.*** (See HB 536, Section 5(1), page 9, line 7).

In conclusion, thank you for your attention to this complex, but significant area of legislative concern. HB 536 provides timely and important consumer protection measures, and on behalf of PhRMA I would like to support its passage.

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